JUL 13 2007

K063641

510(k) Summary of Safety and Effectiveness

Submitter

Shenzhen Creative Industry Co., LTD.
2/F, Block 3, Nanyou Tian'an Industry Town,
Shenzhen, GD
P. R. China-518054
Telephone: +86 755 2643 3514
Fax: +86 755 2643 2832
E-mail: market@creative-sz.com
Company Contact: Nang Jin
Date Summary Prepared: 8-20-2006

Device Name

Trade Name: PC-60, Fingertip Oximeter
Common Name: Pulse oximeter
Classification Name: Pulse Oximeter (21CFR870.2700)
Classification: Class II

Predicate Devices (Legally Marketed Devices)

The predicate device for Non-invasive pulse oximeter, Model PC-60 Fingertip Oximeter is: Nonin Onyx©II Fingertip Oximeter, pulse oximeter, Model 9550, cleared by FDA through 510(k) No. K051107.

Device Description

The Shenzhen Creative Industry Co., LTD, Model PC-60 Fingertip oximeter is to monitor pulse rate and SPO2, for adult and pediatric patients in home use and clinical applications. This monitor is available for sale by the order of a physician or licensed health care professional.

Intended Use

The PC-60 Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient's finger, and indicating the pulse intensity by a bar-graph display. This device is powered by 2 AAA batteries, it is small in size, convenient to use, and easy to carry. This device is applicable for spot-checking of SpO2 and pulse rate in home and clinic for adult and pediatric patients. This device is recommended for use on the index finger, for patients with fingers of 1.0 – 2.2 cm thick.

Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

The Non-invasive pulse oximeter, Model PC-60 is substantially equivalent to the

Nonin Onyx© II Fingertip Oximeter, Model 9550.

The Non-Invasive Pulse oximeter measurement specifications and performance are equivalent to the Nonin Onyx© II Fingertip Oximeter, Model 9550.

Summary of Performance Testing

The PC-60 Fingertip Oximeter substantially has been tested in accordance with the system V & V plan and summary included with the submission using production equivalent units prior to release to market.

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of design control procedure. Shenzhen Creative Industry, LTD quality system confirms to 21CFR820, ISO 9001, ISO13485 and CMDCAS ISO 13485.

Conclusions

As stated above, the PC-60 Fingertip Oximeter is safe and effective and complies with the appropriate medical device standards and is substantially equivalent to the earlier identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Shenzhen Creative Industry Company, Ltd.
C/O Mr. Charles Mack
Principal Engineer
International Regulatory Consultants, LLC
340 Shady Grove Road
Flintville, Tennessee 37335

Re: K063641
Trade/Device Name: PC-60, Fingertip Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 4, 2007
Received: July 9, 2007

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

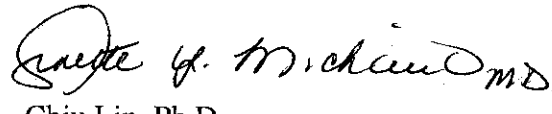
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: PC-60 Fingertip Oximeter

Indications for Use:

Indications For Use	The PC-60 Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through patient's finger, and indicating the pulse intensity by a bar-graph display. This device is powered by 2 AAA batteries, it is small in size, convenient to use, and easy to carry. This device is applicable for spot-checking of SpO_2 and pulse rate in home and clinic for adult and pediatric patients. This device is recommended for use on the index finger, for patients with fingers of 1.0 – 2.2 cm thick.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthe
Infection Control, D

510(k) Number: K063641